



YICHANG SANXIA PHARMACEUTICAL CO., LTD.

NO.8, ZIYANG ROAD, DIANJUN DISTRICT, YICHANG CITY, HUBEI PROVINCE, P.R.CHINA

CERTIFICATE OF ANALYSIS

ISSUING DATE:2012-07-03

PRODUCT NAME:NEOMYCIN SULPHATE -	BATCH NO.:201206054
PACKING:15BOU/DRUM	MFG DATE:2012-06-25
QUANTITY: 675 BOU	EXP DATE:2016-06-24

Items	Specification:EP7	Results
Characteristics	White or yellowish-white powder, odorless or almost, hygroscopic	Complies
Identification	A, B The positive reaction.	Complies
Solubility	Very soluble in water, very slightly soluble in alcohol, practically insoluble in acetone	Complies
PH	5.0-7.5	6.2
Specific optical rotation	+53.5° TO +59.0°	+58.7°
Related Substance (HPLC)	Impurity A	≤2%
	Impurity C	3%-15%
	Any other impurity	≤5%
	Total of other impurities	≤15%
	Disregard limit	≤1%
Sulphate	27.0%-31.0%	28.8%
Loss on drying	≤8%	4.7%
Sulphated ash	≤1.0%	0.2%
Microbiological Enumeration	TAMC ≤1000CFU/g(EP 5.1.4)	20
	TYMC ≤100CFU/g(EP 5.1.4)	<10
Assay	≥680 IU./mg(DRY)	687 IU./mg(DRY) 655 IU./mg(MOIST)
Conclusion: The product meets the requirements of EP7.0		

Analysts:

Yang Peifeng Ma Yongmei Jia Yumei

Supervisor:

Chen Yongqiang

THE BATCH HAS BEEN MANUFACTURED IN FULL COMPLIANCE WITH GMP NUMBER:鄂J0351, ISSUE DATE:2008/12/26, VALIDITY DATE:2013/12/25 AND "BATCH PRODUCTION RECORD CHECKED AND APPROVED."

YICHANG SANXIA PHARMACEUTICAL CO., LTD.
宜昌三峡制药有限公司

YICHANG SANXIA PHARMACEUTICAL CO., LTD.

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

L12090046

Director Técnico S.